

# CONTENTS

<b>CONTENTS</b> .....	<b>1</b>
<b>BACKGROUND</b> .....	<b>1</b>
<b>1. OUTLINE OF THE RISK ASSESSMENT PROJECT</b> .....	<b>2</b>
<b>1.1 Methodology</b> .....	<b>2</b>
<b>1.2 Identification of risks</b> .....	<b>2</b>
<b>1.3 APVMA unacceptable strategic risks</b> .....	<b>3</b>
<b>1.4 Unacceptable Program risks</b> .....	<b>3</b>
<b>1.5 Risk sources</b> .....	<b>3</b>
<b>1.6 Common issues</b> .....	<b>3</b>
<b>1.7 Effective regulation</b> .....	<b>4</b>
<b>2. ANALYSIS OF THE SYSTEMIC ISSUES IDENTIFIED THROUGH THE RISK ANALYSIS</b> .....	<b>4</b>
<b>2.1 Interdependencies</b> .....	<b>4</b>
<b>2.2 Common sources of risk and systemic issues</b> .....	<b>4</b>
<b>3. MONITORING AND REVIEW—INTEGRATING PERFORMANCE AND RISK REPORTING THROUGH THE CORPORATE AND RISK DASHBOARDS</b> .....	<b>5</b>
<b>3.1 APVMA Strategic Planning</b> .....	<b>5</b>
3.1.1 Corporate and Operational Plans .....	<b>5</b>
<b>3.2 APVMA BSC Risk Dashboard</b> .....	<b>6</b>
3.2.1 Organisation of the APVMA BSC Risk Dashboard .....	<b>6</b>
<b>ANNEXES</b> .....	<b>7</b>
<b>Annex A Programs that participated in risk management             workshops</b> .....	<b>7</b>
<b>Annex B Risk management matrix</b> .....	<b>8</b>
<b>Annex C Risk consequence ratings</b> .....	<b>9</b>
<b>Annex D Acronyms and abbreviations</b> .....	<b>10</b>

## TABLES

<b>Table 1 Types of Risks.....</b>	<b>3</b>
<b>Table 2 Outputs, strategies and support outputs for APVMA.....</b>	<b>5</b>

## BACKGROUND

The APVMA's vision is to be recognised both nationally and internationally as a best practice regulator of pesticides and veterinary medicines, with the respect and confidence of governments, the community, the rural sector, chemical users and the chemical industry. It can only achieve this if the risks facing the organisation are also managed in accordance with best practice. Accordingly, the APVMA is committed to undertaking a Risk Assessment and completing a Risk Management Plan every two years using best practice methodologies.

In 2003 a Risk Assessment and Risk Management Plan was completed by Deloitte Touche Tohmatsu. In late 2005 Wyagdon Enterprises reviewed the APVMA's Risk Assessment and completed a new Risk Management Plan. For the first time this plan incorporated Kaplan and Norton's Balanced Scorecard (BSC) methodology whilst adhering to the Australian Standard for Risk Management (AS/NZS 4360:2004). The Plan was completed in May 2006, and in 2007, it won the 2007 Comcover Award for Excellence in Risk Management (Innovation Category).

The most recent review of the APVMA's risks was concluded in February 2008. The review expands upon this earlier work and is again underpinned by AS/NZS 4360:2004 and Kaplan and Norton's BSC methodology (in relation to the reporting and monitoring of risks). The Risk Management Plan integrates closely with the APVMA's Corporate and Operational Plans.

### Purpose of this report

This report outlines the findings of the review and proposes treatments of the resultant risks. In developing the Risk Management Plan a complete review of risks facing the organisation has been undertaken. New risks have been identified and some previously identified risks have been removed or re-categorised. New treatments have been developed for the unacceptable risks that have been identified.

This purpose of this report is to:

- describe the methodology used in the risk assessment and associated plan
- identify the key types of risk and their source, the adequacy of current controls and the key treatments required to ensure that the APVMA can achieve its outputs, vision and mission
- describe the integration of performance and risk management through the APVMA BSC Risk Dashboard (graphic device used to report key performance methods).

This report is divided into the following areas:

- an outline of the project
- an analysis of the systemic issues identified through risk analysis
- a description of the performance monitoring and review framework.

# 1. OUTLINE OF THE RISK ASSESSMENT PROJECT

The risk assessment project was undertaken to ensure that:

- risk assessment focuses on the strategic and business issues
- risk information is integrated into the performance management reporting framework currently used.

The project comprised:

- conducting strategic and Program specific risk assessments (the context provided by the Corporate Plan and strategies)
- identifying the high-level, unacceptable strategic and Program specific risks
- identifying the types of risk and common sources for these unacceptable risks
- identifying treatments for these risks
- reviewing the risk reporting framework.

## 1.1 Methodology

The methodology used for the risk assessment phase of the project was consistent with the Australian Standard for Risk Management (AS/NZS 4360:2004) and ASX Corporate Governance Principles.

Workshops (see Annex A) were held across the organisation and APVMA Program staff identified the sources and impacts of risks to APVMA.

Risks were then scored and consensus sought on the likelihood of the risk occurring and the possible consequences. Current controls were documented and, where appropriate, treatment strategies were developed. Risks were then reviewed by the APVMA's Executive Management Team.

The criteria used by the APVMA to determine whether risks were acceptable or unacceptable are reflected in the qualitative risk analysis matrix at Annex B. A description of the risk consequence ratings is shown at Annex C. The Executive Management Team agreed that risks that were plotted in high risk or extreme risk positions on the matrix were unacceptable and required specific treatment strategies to reduce risk levels.

These risk treatments are detailed against the relevant strategies in the APVMA's Operational Plan. The effectiveness of the treatments and their implementation will be monitored through the Risk Dashboard and reflected in individual performance agreements with senior managers.

## 1.2 Identification of risks

A range of risks, sources, impacts, current controls and their effectiveness and risk levels have been identified across the organisation. Proposed treatment strategies were developed to manage the risks judged as unacceptable.

Table 1 shows the types of risks and how they are defined.

**Table 1 Types of Risks**

Type of Risk	Definition
Strategic	Risks that are one of the following: <ul style="list-style-type: none"><li>• high level and generally impact on the entire organisation</li><li>• driven by uncertainties, for example concerning government policy, the budget, or a change in stakeholder requirements and that relate to the overall direction that the organisation is taking.</li></ul>
Program	Risks that generally relate to operational activities and events that either may occur within a particular Program or an event for which a particular Program has key responsibility and control.

### 1.3 APVMA unacceptable strategic risks

Unacceptable risks are those rated as having risk levels at either the 'high' or 'extreme' levels in accordance with the assessment management matrix shown at Annex B. Unacceptable risks require APVMA to implement treatments that will reduce the risk of the event occurring to an acceptable level.

### 1.4 Unacceptable Program risks

Unacceptable Program risks are grouped according to their level of severity.

### 1.5 Risk sources

A review of the risks revealed the following possible sources of risk for the APVMA:

- legal and regulatory
- operational decision making
- external e.g. emerging scientific technologies
- stakeholders
- quality assurance
- issue and relationship management
- financial, infrastructure, asset management and resource allocation
- compliance
- people and capability building
- information technology and communications
- cost-recovery.

### 1.6 Common issues

An analysis of the sources of APVMA risks revealed the following underlying systemic (or system wide) issues:

- an increased focus on high risk chemicals and implications for national security
- an increasingly complex role in the regulation of agvet chemicals
- stakeholder expectations can be markedly different
- a need for continuous improvement
- a dependency on external agencies for expert advice
- the need to regularly review capability and resource allocations
- an increasing focus on cost recovery and resource allocation

- information technology and business system development
- differing agendas by members of the National Registration Scheme (NRS)
- information security and the management of commercial-in-confidence information
- compliance with government requirements such as the recent transition of the APVMA from the *Commonwealth Authorities and Companies Act 1997* to the *Financial Management and Accountability Act 1997*
- fraud.

## 1.7 Effective regulation

Under powers conferred on it by the agvet Code, the APVMA:

- approves active constituents used in agricultural and veterinary chemical products (agvet)
- registers agvet chemical products
- approves product labels
- issues permits for minor use, or emergency use, or research user of registered or unregistered products
- considers (reviews) the registration of products if there is concern about their quality, safety, or efficacy
- issues licences for manufacture of veterinary chemical products
- ensures marketplace compliance of agvet chemicals with regulatory and registration standards.

If the APVMA is satisfied with the quality, safety and efficacy of the product, the agvet Code states that the APVMA must grant an application for registration. The APVMA must not be so risk averse that it unduly delays granting registration to safe and effective products, but the APVMA must not register a product which is of poor quality, or unsafe, or ineffective.

## 2. ANALYSIS OF THE SYSTEMIC ISSUES IDENTIFIED THROUGH THE RISK ANALYSIS

The risk analysis revealed that the APVMA's systemic issues are:

- the interdependent nature of the strategic and program risks
- the types of risks common across programs.

By focusing on these issues holistically, the APVMA is able to address its systemic issues in an effective and efficient manner. The following sections provide more information on these issues.

### 2.1 Interdependencies

An analysis of the APVMA risks revealed a high degree of interdependencies between all the risks. For example, many of the Program-level risks are sources for the strategic risks.

### 2.2 Common sources of risk and systemic issues

- Systemic issues reflect the close relationship between the type of risk and the common sources of risk. A review of sources across all the significant unacceptable and high-level APVMA strategic and program risks, key result areas (KRAs) and risk categories indicates a pattern of the following systemic issues which have an impact on risk management

- legislation and the regulatory environment
- external dependencies
- an increasingly complex role with unchanged resource levels
- challenges to APVMA decisions
- science quality and high calibre staff.

### 3. MONITORING AND REVIEW—INTEGRATING PERFORMANCE AND RISK REPORTING THROUGH THE CORPORATE AND RISK DASHBOARDS

The APVMA’s integrated framework for risk reporting is centred on the following tools:

- The Operational Plan and Program Plans
- The Corporate Dashboard and the Risk Dashboard (graphic devices used to report key performance metrics).

#### 3.1 APVMA Strategic Planning

##### 3.1.1 Corporate and Operational Plans

The Outputs and Strategies from the APVMA’s Corporate Plan 2006–2009 are shown in Table 7.

**Table 2 Outputs, strategies and support outputs for APVMA**

<b>Outputs</b>	
Regulatory decisions and information supported by evidence-based risk assessments and consistent with national and international standards	Responsive feedback mechanisms and quality assurance and compliance programs that support ongoing chemical product quality and conformance with legislation
<b>Strategies</b>	
Evaluate and consider applications to approve active constituents, register chemicals, approve labels and provide regulatory consents, such as permits following scientific evaluation	Consider stakeholder feedback, including adverse experience reporting
Engage stakeholders to improve awareness and inform policy development and to optimise the regulatory framework within which APVMA operates	Ensure industry compliance with the legislation, including maintenance of quality assurance programs
Review registered chemicals on the basis of their risk	Respond to and manage emerging regulatory issues
<b>Support outputs</b>	
Conduct efficient and effective business management that optimises our use of resources and minimises business risk	Recruit, develop and retain valued and high-performing people

The risk assessment project highlighted the critical nature of the following elements of the strategy map:

- efficient and effective regulation of pesticides and veterinary medicines up to the point of retail sale
- efficient and effective business management that optimises APVMA use of resources and minimises business risks
- regulatory decisions and information that are supported by evidence-based risk assessments and are consistent with national and international standards
- cooperation with the chemical industry to ensure compliance with the legislation, including the maintenance of quality assurance programs.

- Each year the APVMA develops an Operational Plan using Kaplan and Norton's Balanced Scorecard (BSC) methodology that translates the strategies into actions and allows a clear communication of strategy, objectives, performance measures and projects to all stakeholders, including staff.

The BSC methodology integrates performance and risk management and the scorecard demonstrates the comprehensive manner in which APVMA addresses the sources of its unacceptable risks. The strategy map drives the performance management aspects, and the risk management information is mapped against the key strategies and goals of the map. Specifically, the scorecards map the current controls and treatment strategies against APVMA critical strategies.

The APVMA is thus able to manage the interdependent relationships between the risks of each key strategy while addressing the systemic issues. This approach assists the APVMA in its risk-based allocation of resources.

## 3.2 APVMA BSC Risk Dashboard

The BSC Risk Dashboard is a performance management tool for the Executive and Advisory Board of the APVMA to monitor the progress of key treatments and to provide feedback on performance against key risks. The feedback on risk management is derived from the implementation strategies for unacceptable risks.

### 3.2.1 Organisation of the APVMA BSC Risk Dashboard

The Risk Dashboard is divided according to the following traditional BSC perspectives (or categories):

- stakeholders and client expectations
- business processes
- financial issues
- people, learning and development.

The perspectives are referenced against the themes of operational excellence, stakeholder satisfaction and informed policy.

The BSC Risk Dashboard integrates unacceptable risks and their treatments into the perspectives outlined above. By integrating performance and risk through the same perspectives and themes, members of the APVMA Advisory Board and Executive gain a multidimensional understanding of the strategic issues and other issues affecting the organisation.

# ANNEXES

## Annex A Programs that participated in risk management workshops

The following five APVMA Programs participated in the two risk management workshops held to identify the risks, their sources and impacts, and to identify current controls and their effectiveness, levels of risk and treatment strategies.

- Pesticides Program
- Veterinary Medicines Program
- Corporate Services Program
- Legal Program
- Regulatory Strategy and Compliance Program.

## Annex B Risk management matrix

### Qualitative Risk Analysis Matrix

Likelihood	Consequences				
	Insignificant 1	Minor 2	Moderate 3	Major 4	Severe 5
Almost certain A	M	H	H	E	E
Likely B	M	M	H	H	E
Possible C	L	M	M	H	E
Unlikely D	L	M	M	M	H
Rare E	L	L	M	M	H

Risk level:	E	Extreme risk	Detailed action or plan required
	H	High risk	Needs executive management attention
	M	Moderate risk	Specify management responsibility
	L	Low risk	Managed by routine procedures
Likelihood:	A	Almost certain	Expected in most circumstances
	B	Likely	Will probably occur in most circumstances
	C	Possible	Could occur at some time
	D	Unlikely	Not expected to occur
	E	Rare	Exceptional circumstances only
Consequence:	5	Severe	Would stop achievement of functional goals or objectives
	4	Major	Would threaten functional goals or objectives
	3	Moderate	Necessitates significant adjustment to overall function
	2	Minor	Would threaten an element of the function
	1	Insignificant	Lower consequence

Unacceptable risks are those classified as either High or Extreme according to the table shown above.

## Annex C Risk consequence ratings

Rating		Area of impact				
		Operational outputs	Financial	Resources	Reputation	Business continuity
<b>Severe</b>	5	Greater than 10% impact on targets	Financial loss greater than \$1million	<ul style="list-style-type: none"> <li>Loss of 10% of key staff</li> <li>Destruction or serious damage to a significant amount of key physical or information assets</li> </ul>	<ul style="list-style-type: none"> <li>Federal Government inquiry</li> </ul>	<ul style="list-style-type: none"> <li>Loss of service capacity for more than 3 weeks</li> </ul>
<b>Major</b>	4	Up to 10% impact on targets	Financial loss from \$250 000 up to \$1million	<ul style="list-style-type: none"> <li>Injury to staff</li> <li>Loss of critical mass of staff</li> <li>Destruction or serious damage to key physical or information assets</li> </ul>	<ul style="list-style-type: none"> <li>APVMA adversely discussed in Parliament</li> <li>Sustained national press coverage</li> </ul>	<ul style="list-style-type: none"> <li>Loss of service capacity for up to 1 week</li> </ul>
<b>Moderate</b>	3	Up to 5% impact on targets	Financial loss from \$50 000 up to \$250 000	<ul style="list-style-type: none"> <li>Loss of 5% of key staff</li> <li>Damage to physical or information assets</li> </ul>	<ul style="list-style-type: none"> <li>Adverse comments in press</li> </ul>	<ul style="list-style-type: none"> <li>Loss of service capacity for between 4 and 12 hours</li> </ul>
<b>Minor</b>	2	Up to 2% impact on targets	Financial loss from \$10 000 up to \$50 000	<ul style="list-style-type: none"> <li>Temporary loss of key staff</li> </ul>	<ul style="list-style-type: none"> <li>Adverse customer comments</li> </ul>	<ul style="list-style-type: none"> <li>Loss of service capacity for between 2 and 4 hours</li> </ul>
<b>Insignificant</b>	1	Minor impact on targets	Financial loss up to \$10 000	<ul style="list-style-type: none"> <li>Minor impact on resources</li> </ul>	<ul style="list-style-type: none"> <li>Internal impact only</li> </ul>	<ul style="list-style-type: none"> <li>Loss of service capacity for up to 2 hours</li> </ul>

Notes: Risks should be assessed in terms of the 'normal' consequence of occurrence

When assessing consequence, each risk should be considered in relation to its cumulative effect in the period under review. If the cumulative effect increases the magnitude of the consequence, then the highest identified impact rating should be used.

When selecting the desired consequence rating under the 'non-financial' and 'financial' consequence areas, it is important to keep a balanced perspective of the ultimate impact of the risk to APVMA. The consequence rating that represents the highest impact on APVMA's operations should be selected (i.e. if a risk is both a moderate financial risk and a major reputation risk, rate the risk as 'major').

Financial impacts include actual losses (e.g. fraud) but not routine budget fluctuations in income

## Annex D Acronyms and abbreviations

AERP	Adverse Experience Reporting Program
Agvet	Agricultural and veterinary chemical products
AHRI	Australian Human Resources Institute
ANAO	Australian National Audit Office
APVMA	Australian Pesticides and Veterinary Medicines Authority
AAT	Administrative Appeals Tribunal
BCP	Business Continuity Plan
BSC	Balanced Scorecard
CCC	Community Consultative Committee
CRP	Chemicals Review Program
CS	Corporate Services
DAFF	Department of Agriculture, Fisheries and Forestry
DPP	Director of Public Prosecutions
DMZ	Demilitarised Zone
DSD	Defence Signals Directorate
EARS	Electronic application registration system
EDMS	Electronic Document Management Scheme
EL	Executive Level
EM	Executive Management
ESI	Export Slaughter Intervals
FAISD	First Aid Instructions and Safety Directions
FSANZ	Food Standards Australia New Zealand
GMP	Good Manufacturing Practice
HR	Human Resources
ILC	Industry Liaison Committee
ILS	Integrated Leadership System
IPAD	Individual Performance and Development
KRA	Key Result Areas
MLS	Manufacturing Licensing Scheme
MORAG	Manual of Requirements and Guidelines
MRL	Maximum Residue Limit
NRS	National Registration Scheme
OGTR	Office of the Gene Technology Regulator
OH&S	Occupational Health and Safety
OECD	Organization for Economic Cooperation and Development
PIMC	Primary Industries Ministerial Council
PSIC	Product Safety and Integrity Committee
PM	Program Manager
QA	Quality Assurance
RBA	Reserve Bank of Australia
SLA	Service Level Agreement
RLC	Registration Liaison Committee
RCC	Regulatory Compliance Committee
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
UPS	Uninterruptible Power Supply
VICH	International Cooperation of Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VOIP	Voice over Internet Protocol